43

FILED ENTERED
LODGED RECEIVED
SEP 30 1998
AT BALTIMORE
CLERK U.S. DISTRICT COURT
DISTRICT OF MARYLAND
BY DEPUTY

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GLAXO WELLCOME, INC. and
GLAXO GROUP LIMITED,
Plaintiffs

v.

PHARMADYNE CORPORATION, et al.,
Defendants

CIVIL NO. AMD 96-455

...o0o...

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Contents

Glaxo Wellcome, Inc. and Glaxo Group Limited (together "Glaxo"),[1] instituted this action against Pharmadyne Corporation and several affiliated entities for infringement of patents related to its Zantac medication. Defendants counterclaimed for a declaratory judgment on several grounds. A bench trial commenced on November 12, 1997, and concluded on February 5, 1998. The parties have submitted post-trial briefs, which have been carefully considered. I have carefully considered the entire evidentiary record of the case, and render herein findings of fact and conclusions of law in accordance with Fed. R. Civ. P. 52(a).

[1]Glaxo Group Limited is the parent corporation headquartered in the United Kingdom. Glaxo Wellcome, Inc. is a North Carolina corporation which sells Glaxo Group Limited products in the United States.

patent number 5,068,249, entitled Aqueous Ranitidine Compositions Stabilized with Ethanol issued to Glaxo.

III. PHARMADYNE'S DEVELOPMENT OF THE ACCUSED PRODUCT

A. Introduction

Pharmadyne's Ranitidine Oral Solution USP product covered by ANDA 74-794 (the "accused product") contains 12.5% propylene glycol and 25% sorbitol, by weight/volume of the total formulation. The accused product as filed under the ANDA 74-794 is a generic ranitidine oral solution composed of the following:

Ingredient	Quantity per 1 mL
1. Ranitidine Hydrochloride	16.8 mg (equiv. to 15 mg/ml ranitidine)
2. Dibasic Sodium Phosphate	13.61 mg
3. Citric Acid Anhydrous	1.0 mg
4. Saccharin Sodium	1.0 mg
5. Sorbitol Solution	250 mg
6. Propylene Glycol	125 mg
7. Methylparaben	1.8 mg
8. Propylparaben	0.2 mg
9. Natural Peppermint Extract	5.0 mg
10. Purified Water	Q.S.

The regulatory specification for the pH of the ANDA product is 6.7 to 7.5. (PX-71, p. P01515.)

Samples from a 500 liter batch of the ANDA product achieved a pH of 7. (PX-71, pp. 01559-60.) Samples from the 500 liter ANDA batch were packaged in (i) 16 oz. PET bottle

performs the same function in the same way to obtain the same result as the 7.5% ethanol in the '249 patent.

Recently, the Supreme Court reaffirmed the validity of the doctrine of equivalents and clarified the scope of the doctrine. *See Warner-Jenkinson Co.*, 520 U.S. ___, 117 S.Ct. 1040. The Court held that the doctrine requires an evaluation of the accused product to determine whether it contains elements equivalent to each claimed element of the patented invention. *Warner-Jenkinson*, 520 U.S. at ___, 117 S.Ct. at 1054. "An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element." *Id.* In the context of this case, additional factors that need to be considered under the doctrine include: 1) whether persons skilled in the art knew that propylene glycol was interchangeable with ethanol; 2) whether there is substantial evidence that Pharmadyne simply copied the '249 patent; 3) whether there is evidence of independent development by Pharmadyne; and 4) whether Pharmadyne designed around the '249 patent. *See Warner-Jenkinson*, 520 U.S. ___, 117 S.Ct. at 1052-53.

2. Application to the facts in the case at bar

Here, Glaxo met its burden of establishing that the propylene glycol in the accused product performs the same work in substantially the same way and accomplishes the same result as the ethanol in Glaxo's '249 patent.

Determination of whether an accused product infringes requires a two step analysis. First, the court must construe the claims of the allegedly infringed patent. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098 (Fed.Cir. 1996), *cert. denied*, ___ U.S. ___, 117 S.Ct. 1244 (1997); *Tanabe Seiyaku Co.*,

Hempenstall in including the 37°C data in his declaration. On cross-examination, Pharmadyne raised the issue of whether the statistician had actually analyzed the data for that particular study and whether the figures Dr. Hempenstall submitted in his declaration were correct. Dr. Gillian Amphlett of Glaxo's Statistics Divisions expressed uncertainty at her deposition whether the 37°C figures had been analyzed and forwarded to Dr. Hempenstall. (Hempenstall Tr. at 4331-34.) She could not recall performing such an analysis. Dr. Hempenstall recalled otherwise.

In light of the fact that Dr. Carstensen conceded that he never reviewed the raw data from any of the comparative studies used by Glaxo to support its patent claim, and in light of Pharmadyne's failure to actually establish that the data provided to the PTO was false or inaccurate, I am persuaded that Dr. Hempenstall's recollection is reliable. There is no evidence that Dr. Hempenstall acted for any reason other than the reasons he stated. Pharmadyne essentially has asked the Court to find the requisite intent and materiality for inequitable conduct by Dr. Hempenstall in the exclusion of certain data from his declaration. Dr. Hempenstall excluded both favorable and unfavorable data and presented bona fide reasons for his decision to include and exclude data. Accordingly, I do not find inequitable conduct by Dr. Hempenstall.

V. CONCLUSION

For the reasons set forth above, a judgment order shall be entered herewith in favor of Glaxo.

Filed: September 30, 1998

ANDRE M. DAVIS
UNITED STATES DISTRICT JUDGE